



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/287,332	04/07/1999	KAARE M. GAUTVIK	16777/309	6190

7590 10/21/2002

FOLEY AND LARDNER
3000 K STREET NW SUITE 500
WASHINGTON, DC 200075109

EXAMINER

LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
----------	--------------

1647

DATE MAILED: 10/21/2002

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/287,332

Applicant(s)

GAUTVIK ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,39 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38,39 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Formal Matters

- A. Amendment E, filed 7/15/02, has been entered into the record.
- B. Claims 21-56 were pending in this application. Claims 21-37, 40 and 42-56 are cancelled. Therefore, claims 38, 39 and 41 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cite in full, in a previous Office Action.

2. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

- A. Claims 38, 39 and 41 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 4-5 of the Office Action dated 1/15/02. Applicants argue that the use of various leader sequences in various microorganisms were well-known in the art at the time of the present invention. This argument has been considered, but is not deemed persuasive. First, the issue that various leader sequences in various microorganisms were well-known in the art at the time of the present invention is not in question. The issue is the fact that the specification discloses that the production of full-length PTH in a microorganism was not previously possible since PTH is degraded (page 2, line 23 - page 3, line 8). The specification teaches (page 4, lines 20-33) only teaches the use of a vector comprising a yeast mating factor signal sequence to express hPTH and that this expression has only been performed in E. coli and yeast. Therefore, one of ordinary skill in the art would not have been able to use the present invention by using an expression system other than that taught by the present specification.

3. Claim Rejections - 35 USC § 112, second paragraph

- A. The rejection of claim 38, 39 and 41 under 35 USC 112, second paragraph, has been withdrawn in view of the fact that, as argued by Applicants, the use of various signal sequences in various expression systems does not render the invention indefinite.
- B. The rejection of claims 38 and 41 under 35 USC 112, second paragraph, has been withdrawn since Applicants have amended the claims to remove the word “component.”

Art Unit: 1647

4. Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 38, 39 and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 5,420,242. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the present invention recite a cell-free medium obtained following the growth of a microorganism wherein the PTH fraction, which has been cleaved from its signal sequence, consists of hPTH(1-84) and a method of obtaining intact hPTH(1-84). Claim 10 of the patent recites a DNA encoding a yeast mating factor signal sequence linked to hPTH wherein this DNA can transform a yeast cell to express and secrete intact, functional hPTH.

Given claim 10 of the patent, which claims that the DNA is used to produce PTH which is then secreted into the medium, it would have been obvious to one of ordinary skill in the art to have obtained a cell-free medium comprising this PTH since claim 10 of the patent recites that the hPTH is, in fact, secreted into the medium. Having known that intact PTH is secreted into the medium, it would have then been obvious for one of ordinary skill in the art to have purified this protein by isolation techniques which were well-known in the art at the time of the present invention. In fact, obtaining cell-free extracts of hPTH were taught in column 19, line 60 – column 20, line 5.

B. Claims 38, 39 and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 5,010,010 (see especially claims 1 and 23). Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the present invention recite a cell-free medium obtained following the growth of a microorganism wherein the PTH fraction, which has been cleaved from its signal sequence, consists of

Art Unit: 1647

hPTH(1-84) and a method of obtaining intact hPTH(1-84). Claim 1 of the patent recites a DNA encoding a yeast mating factor signal sequence linked to hPTH wherein this DNA can transform a yeast cell to express and secrete intact, functional hPTH. Claim 23 of the patent recites the yeast cell *per se*.

Given the claims of the patent, which claim that the DNA is used to produce PTH which is then secreted into the medium, as well as claiming the yeast cell, it would have been obvious to one of ordinary skill in the art to have obtained a cell-free medium comprising this PTH since the claims of the patent recite that the hPTH is, in fact, secreted into the medium. Having known that intact PTH is secreted into the medium, it would have then been obvious for one of ordinary skill in the art to have purified this protein by isolation techniques which were well-known in the art at the time of the present invention. In fact, obtaining cell-free extracts of hPTH were taught in column 10, lines 20 – 45.

C. Claims 38 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,146,852. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the present invention recite a cell-free medium obtained following the growth of a microorganism wherein the PTH fraction, which has been cleaved from its signal sequence, consists of hPTH(1-84). Claims 1 and 2 of the patent recites a process for producing hPTH by transfecting PTH linked to a leader sequence wherein the cell cleaves the leader sequence to express and secrete intact, functional hPTH.

Given claims 1 and 2 of the patent, which claim a process for producing recombinant PTH which is secreted into the medium, it would have been obvious to one of ordinary skill in the art to have obtained a cell-free medium comprising this PTH since claim 1 of the patent recites that the hPTH is, in fact, secreted into the medium and is purified. The fact that the PTH is purified implies that it is cell-free. In fact, obtaining cell-free extracts of hPTH were taught in Examples 8, 12 and 13 of the patent.

5. Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Art Unit: 1647

A. Claim 41 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1 and 2 of prior U.S. Patent No. 6,146,852. This is a double patenting rejection. Claim 41 of the application recites obtaining cell-free medium and treating the medium to isolate hPTH(1-84). Claim 1 of the patent recites culturing yeast cells to secrete intact PTH and purifying PTH from the medium. Therefore, both claim 41 of the present invention and claims 1 and 2 of the patent recite a method of obtaining intact PTH, including hPTH.

6. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 38 and 39 are rejected under 35 USC 102(b) as being anticipated by Breyel et al. (Third Eur. Congress Biotech – cited by Applicants). The claims recite a cell-free medium obtained following the growth of a microorganism wherein said medium comprises hPTH. Breyel et al. teach expression of hPTH(1-84) in E. coli. and that extracts were obtained (“Summary” and page 366 under “Identification of hPTH from bacterial extracts”). These extracts were cell-free since the supernatants of sonicated and centrifuged cells were used (page 364 under “Detection of PTH activity in bacterial extract”). Though there is no teaching of PTH linked to a signal sequence, Breyel et al. meet the limitation of the claim since, according to the claims of the present invention, the leader sequence is cleavable upon production of hPTH.

Art Unit: 1647

B. Claims 38, 39 and 41 are rejected under 35 U.S.C. 102(e) as being unpatentable by Gautvik et al. (U.S. Patent No. 6,146,852). The claims of the present invention recite a cell-free medium obtained following the growth of a microorganism wherein the PTH fraction, which has been cleaved from its signal sequence, consists of hPTH(1-84). Claims 1 and 2 of the patent recites a process for producing hPTH by transfecting PTH linked to a leader sequence wherein the cell cleaves the leader sequence to express and secrete intact, functional hPTH.

Given claims 1 and 2 of the patent, which claim a process for producing recombinant PTH which is secreted into the medium, it would have been obvious to one of ordinary skill in the art to have obtained a cell-free medium comprising this PTH since claim 1 of the patent recites that the hPTH is, in fact, secreted into the medium and is purified. The fact that the PTH is purified implies that it is cell-free. In fact, obtaining cell-free extracts of hPTH were taught in Examples 8, 12 and 13 of the patent.

Furthermore, claim 41 of the application recites obtaining cell-free medium and treating the medium to isolate hPTH(1-84). Claim 1 of the patent recites culturing yeast cells to secrete intact PTH and purifying PTH from the medium. Therefore, both claim 41 of the present invention and claims 1 and 2 of the patent recite a method of obtaining intact PTH, including hPTH.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 21, 2002

